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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/040,244	FORCE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/25/06; 1/16/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11, 20-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission, filed on 4/25/06, has been entered

Applicant's amendment, filed 4/25/06, been entered.

Claims 8-11 and 20-21 have been amended.

Claim 31 has been canceled.
Claims 1-7, 12-19 and 29 have been canceled previously.

Applicant's amendment, filed 1/16/07, been entered.

Claims 8-11 and 20-21 have been amended.

Claims 8-11, 20-28 and 30 are pending.

Claims 8-11 and 20-21 are under consideration in the instant application.

Claims 22-28 and 30 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to nonelected inventions.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

This Action will be in response to applicant's amendments / arguments, filed 4/25/06 and 1/16/07.

The rejections of record can be found in the previous Office Action.

3. Claims 8-11 and 20-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-11 and 20-21 are indefinite in the recitation of "CD40L enhancer antibody (Alexis)" because its characteristics are not known. The use of "CD40L enhancer antibody (Alexis)" as the sole means of identifying the claimed antibody renders the claim indefinite because "CD40L enhancer antibody (Alexis)" is merely laboratory designations which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct hybridomas / cell lines.

Applicant is invited to clarify the metes and bounds of the claimed "CD40L enhancer antibody (Alexis)" and to provide the appropriate Deposit Accession Number, if appropriate to obviate this rejection.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The previous rejection under 35 U.S.C. 112, first paragraph, enablement with respect to claim 31 has been obviated by the cancellation of this claim.

6. Claims 8-11 and 20-21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention
It is apparent that the "CD40L enhancer antibody (Alexis)" is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Upon amending the instant claims to recite "human anti-human CD40 antibody", the previous rejections under 35 U.S.C. § 102(e) as being anticipated de Boer (U.S. Patent No. 5,874,082) and Siegall (US 2004/0235074 A1) have been withdrawn.

New Grounds of Rejection have been set forth herein to address the well known construction and use of human antibodies in human diagnostic and therapeutic regimens at the time the invention was made to address the recitation of "human anti-human CD40 antibody".

9. Claims 8-11 and 20-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over de Boer (U.S. Patent No. 5,874,082) (1449; #DR) in view of the well know use of human antibodies in the human diagnostic and therapeutic regimens at the time the invention was made as taught by Tomizuka et al. (PNAS 97: 722-727, 2000) (1449; #UUR) AND/OR Ahuja et al. (U.S. Patent No. 6,482,411) (892; of record) AND/OR Kucherlapati et al. (U.S. Patent No. 6,150,584) (1449; #GR).

The teachings of antagonistic anti-CD40 antibodies by de Boer et al. are of record and reiterated herein.

De Boer et al. differs from the claimed invention by the well known construction and use of human antibodies in human diagnostic and therapeutic regimens at the time the invention was made.

De Boer et al. teach both agonistic and antagonistic anti-CD40 antibodies (see entire document). De Boer et al. disclose that all anti-CD40 known in the art have a stimulatory effect on B cells (column 2, paragraph 3) and teach antagonistic anti-CD40 antibodies (see Summary of the Invention, Detailed Description of the Invention and Claims). De Boer et al. teach that recombinant forms of antibodies and antibody fragments as well as pharmaceutical compositions thereof can be used for a variety of procedures (see Detailed Description, particularly columns 5-10). De Boer et al. teach a variety of assays to test anti-CD40 antibodies (e.g. B cell proliferation assay, B cell activation assay, immunoglobulin quantification) (see entire document) and that CD40 epitopes can be identified (see column 7, paragraph 4 - column 8, paragraph 2).

The products of the instant claims and the prior art are defined in terms of certain functional characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Given the properties of antagonistic anti-CD40 antibodies, including a number of binding and functional assays taught by de Boer, the claimed binding and functional properties of anti-CD40 antibodies would have intrinsic or expected properties associated with said antagonistic taught by the prior art.

The following references have been added to support the well known construction and use of human antibodies in human diagnostic and therapeutic regimens at the time the invention was made to address the recitation of "human anti-human CD40 antibody".

Tomizuka et al. (PNAS 97: 722-727, 2000) teach the use of double trans-chomosomic mice in the production of human antibodies to antigens of interest for studying in vivo functions and therapeutic products (see entire document, including the Abstract, pages 722-723, 727).

Ahuja et al. (U.S. Patent No. 6,482,411) teach the generation of human antibodies in the generation of therapeutic anti-CD40 antibodies of interest (see entire document, particularly columns 41-45; Anti-CD40 Antibodies From Human Lymphocytes; Transgenic Mice Containing Human Antibody Libraries) as well as humanized antibodies (see columns 45-50; Humanized Anti-CD40 Antibodies).

Kucherlapati et al. (U.S. Patent No. 6,150,584) teach the use of human antibodies derived from immunized xenomice to generate therapeutic antibodies to antigens of interest (see entire document), including the leukocyte marker CD40 (see column 9, paragraph 6).

It would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of the secondary references to advantages of therapeutic antibodies that were fully human which contain immunospecific regions with fully human characteristics such as the convenience of recombinant technology and to avoid undesired immune responses to antigens of interest to CD40 as taught by de Boer et al. to obtain antagonistic human anti-human CD40 antibodies with the properties claimed. Further, one of ordinary skill in the art at the time the invention was made would have been motivated to employ the well known methods of generating human antibodies as taught by Tomizuka et al. (see the Abstract, pages 722-723, 727), Ahuja et al. (see columns 41-45), and Kucherlapati et al. (see entire document, including Background Art on columns 1-2, to take advantages of therapeutic antibodies that were fully human which contain immunospecific regions with fully human characteristics (e.g., convenience of recombinant technology, to avoid undesired immune responses) to antigens of interest, including CD40 with antagonistic properties as taught by de Boer et al. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. With respect to the teachings of antagonistic anti-CD40 antibodies by de Boer et al. (U.S. Patent No. 5,874,082) (1449; #DR), the following is noted.

Applicant's amendments / arguments, filed 4/25/06 and 1/16/07, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

As pointed out previously, the products of the instant claims and the prior art are defined in terms of certain functional characteristics.

Also, comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons.

Again, applicant's reliance upon the comparison of the prior art antagonistic 5D12 CD40-specific antibody with the instant Example 6, pages 68-70 and Figure 10 of the instant specification is acknowledged.

However these comparisons and results were derived under certain assay conditions.

In contrast to applicant's observations with the 5D12 antibody,
Example 5 on columns 18-19 of de Boer do teach:
"Very potent inhibition occurred. At concentrations as low as 10 ng/ml each, the three anti-CD40 mAbs 5D12, 3C6 and 3A8 inhibited B cell proliferation completely. Half-maximal inhibition was found at about 1 ng/ml."

Therefore, the inhibition taught by the reference does anticipate the claimed limitations as they read on inhibiting B cell proliferation when the concentration of the antibody is in the range of 0.1 μg /ml to 10 μg/ml, as encompassed by the instant claims.

Given the properties of both agonistic and antagonistic anti-CD40 antibodies, including a number of binding and functional assays taught by de Boer, the claimed binding and functional properties of anti-CD40 antibodies would have inherent properties associated with said agonistic and antagonistic taught by the prior art.

Further, applicant failed to rebut prima facie showing anticipation absent objective evidence such as side-by-side testing that would address the thrust of the examiner's rejection and establish the lack of intrinsic or expected properties of antagonistic anti-CD40 antibodies in the prior art rejection.

Applicant's arguments have not been found to be persuasive.

11. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Applicant's amendment, filed 1/16/07, respectfully request that the following double patenting rejections be held in abeyance until allowable subject matter has been indicated.

It is noted that the double patenting rejections have been updated to the status of related applications and U.S. Patents.

For example, it is noted that previously, a provisional rejection was made over copending application USSN 09/844,684, now U.S. Patent No. 7,063,845.

13. Claims 8-11 and 20-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 1-30 of U.S. Patent No. 7,063,845 and

over claims 1-9, 17-18 and 20-21 of U.S. Patent No. 7,193,064.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or nearly the same anti-CD40 antibodies. Although the instant claims do not recite specific anti-CD40 cell lines or hybridomas expressing said antibodies, such cell lines expressing antibodies were well known and practiced in the antibody art either in the producing of said antibodies (e.g. monoclonal antibody technology or recombinant antibody technology) at the time the invention was made. The patented claims anticipate or render obvious the instant pending claims.

14. Claims 8-11 and 20-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending application USSN 11/633,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or nearly the same anti-CD40 antibodies. Although the instant claims do not recite cell lines or hybridomas expressing said antibodies, such cell lines expressing antibodies were well known and practiced in the antibody art either in the producing of said antibodies (e.g. monoclonal antibody technology or recombinant antibody technology) at the time the invention was made. Although, the instant claims are drawn to human antibodies and the copending claims do not recite human antibodies per se, it was well practiced and known by the ordinary artisan to employ various antibody forms, including human antibodies in clinical practice. In addition to the interacting with human cell receptors and interactions, human antibodies had the well known advantage of being less immunogenic and of having an increased half-life in human patients.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. No claim allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 23, 2007